CHAPTER 3

Addressing health care errors under Medicare

RECOMMENDATIONS

3A The Secretary should establish patient safety as a quality improvement priority for Medicare and should take steps to minimize the incidence of preventable errors in the delivery of care provided to beneficiaries.

3B The Secretary should support and make use of ongoing public and private error-reduction initiatives—including those that promote incident reporting by providers, analysis of root causes and patterns in occurrence, and dissemination of information designed to prevent recurrence—through Medicare's policies and quality improvement activities.

3C The Congress should enact legislation to protect the confidentiality of individually identifiable information relating to errors in health care delivery when that information is reported for quality improvement purposes.

3D The Secretary should consider opportunities for minimizing avoidable errors in health care delivery through coverage and payment policies, quality measurement initiatives, and quality improvement programs.

3E The Secretary should work with providers and other stakeholders to identify and promote effective and efficient processes, structures, and activities for reducing preventable errors and to set progressive targets for improvement in patient safety through Medicare's quality improvement programs.

3F The Secretary should not establish requirements that specify maximum tolerance rates of errors in health care delivery under Medicare's conditions of participation for health care providers.

3G The Secretary should fund research to study appropriate use of autopsies and to evaluate approaches for using information derived from autopsies in health care quality improvement and error-reduction initiatives.

CHAPTER 3

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In this chapter

- Errors: a critical health quality problem
- Resources for addressing health care errors
- Minimizing preventable errors under Medicare

Preventable errors in health care delivery contribute to unnecessary patient injuries and health system costs. Reducing errors in the care provided to Medicare beneficiaries could improve beneficiaries' health and functioning and reduce program costs. The experience of other potentially dangerous and safety-conscious industries has shown that errors can be reduced by improving the systems and processes associated with health care delivery and by creating an environment in which errors are seen as opportunities for learning. Therefore, MedPAC recommends that Medicare establish patient safety as a quality improvement priority and take steps to reduce errors in the care provided to beneficiaries.

Health care providers, researchers, policymakers, and others concerned with the public's health have voiced a call to increase patient safety by addressing errors in the delivery of health care. Responding to and amplifying this call, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry selected reducing health care errors as one of six national aims for improvement (1998). Health care leaders envision a day when the industry works systematically to avoid preventable errors, actively identifies and openly acknowledges them when they do occur, makes commensurate reparations to injured parties, identifies root causes of the problems, and takes whatever steps are necessary to see that the industry collectively avoids similar errors in the future.

The Medicare Payment Advisory Commission (MedPAC) has considered Medicare's role in advancing toward this goal. This chapter presents MedPAC's initial findings and recommendations on how the program might minimize preventable errors. It begins by characterizing the nature and extent of the problem. It then looks at error-reduction theories, methods, and mechanisms and highlights exemplary activities and initiatives. The chapter describes Medicare's current policies for addressing errors, then identifies other approaches that might be taken as part of an improved and refocused effort. It then presents MedPAC's analysis of Medicare's potential to enhance the safety of beneficiary care through increased effort to avoid misuse of medications and through improved use of hospital autopsies—two issues of current policy interest.

Based on the considerations and findings described in this chapter, the Commission recommends that Medicare establish patient safety as a quality improvement priority. The Secretary of Health and Human Services should ensure that the program acts to reduce errors through existing mechanisms, works with providers and others to identify and promote effective and efficient error-reduction processes, and supports ongoing public and private safety initiatives. To promote the success of these initiatives, the Congress should enact legislation to protect the confidentiality of information about occurrences of error when reported for quality improvement purposes. The Secretary should define and regularly update target rates of improvement in patient safety, rather than specify and enforce maximum tolerance rates of errors.

While the Commission does not currently offer specific recommendations for addressing medication errors, it notes that the problem is a source of preventable costs and patient injuries and that some hospitals have reported savings and improved patient care through use of automated systems for entering physicians' medication orders.

MedPAC believes that improved use of autopsies can aid in reducing errors as well as advance the field of medicine and enhance individual physicians' knowledge. Therefore, the Commission calls on the Secretary to fund research to study appropriate use of autopsies and to evaluate approaches for using information derived from autopsies in health care quality improvement and error-reduction initiatives.

Errors: a critical health quality problem

Noted health care researcher and analyst Lucian Leape (1994) describes errors as unintended actions or failures to act, and actions or inactions that do not achieve their intended outcomes. By this definition, not all errors are preventable. Sometimes, poor outcomes are a predictable but unavoidable result of incomplete knowledge or imperfect technology, as in instances when a laboratory test with a known error rate returns a false positive or negative finding. But other health care delivery errors can be both anticipated and prevented. Doing so is fast becoming a national priority for quality improvement.

Opportunities for error are compounded by the complex and interrelated factors—human, systemic, and technical—associated with health care delivery today. Individual physicians, nurses, pharmacists, other health care practitioners, and patients inevitably make mistakes in judgment, overlook a symptom, fail to use medication or equipment properly, or misinterpret a finding. The health care processes and systems used by health care organizations and facilities, in some cases influenced by payers or other external forces, largely determine the extent to which opportunities for error will arise. Furthermore, the devices, machines, medications, and other equipment used in treating and diagnosing patients play an important role in determining health care safety and can also serve as a source of error.

A growing body of health services research literature has illuminated both the extent and the implications of errors in health care delivery. By extrapolating findings from the Harvard Medical Practice Study, a study of New York state medical records, Leape (1994) estimated that "180,000 people die each year partly as a result of iatrogenic injury, the equivalent of three jumbo-jet crashes every two days." Studies of such injuries consistently show that many are due to preventable errors. For example, in another facet of the Harvard Medical Practice Study, Leape and colleagues (1993) found that injuries attributable to medical treatment occurred in 3.7 percent of the hospitalizations evaluated, and that more than two-thirds of those injuries were due to errors. While most injuries did not have lasting effects on patient health, 2.6 percent caused permanently disabling injuries and 13.6 percent resulted in death (Brennan et al. 1991).

The Harvard Medical Practice Study also provided insight on the relative frequency of the types of errors occurring in hospitals that result in patient injuries. Of

the injuries attributable to error, 35 percent involved the performance of procedures or operations, 22 percent related to failures of prevention, 14 percent were diagnostic errors, 9 percent medication errors, and 2 percent were classified as system or other errors, such as defective equipment or supplies (Leape et al. 1991).[1]

Errors in ordering, transcribing, dispensing, and administering medications result in adverse drug events (ADEs) that are costly and often preventable. The Adverse Drug Event Prevention Study, which looked at data from two tertiary care hospitals, found that such events occurred in 6.5 percent of admissions; of these, 28 percent were judged preventable (Bates et al. 1995). Researchers estimated that hospital costs for patient care were increased by $2,595 per event overall and $4,685 per event for the subset of events classified as preventable, which were more severe, on average (Bates et al. 1997). Another study involving one tertiary care hospital's records found that ADEs occurred in 2.4 percent of admissions during a three-year period. These events were associated with significantly longer hospital stays, increased costs, and an almost twofold increased risk of death (Classen et al. 1997).

Despite continuing advancement in diagnostic capability, errors in diagnosing patients are common and can result in adverse outcomes. Research conducted since 1938 has consistently shown that postmortem findings differ from pre-death clinical diagnoses between 35 percent and 47 percent of the time (Leape 1994, Lundberg 1998).[2] One recent study found that 45 percent of autopsies revealed one or more undiagnosed causes of death, two-thirds of which were considered treatable (Nichols et al. 1998). Another found that malignant neoplasms discovered at autopsy were the underlying cause of death in 57 percent of deceased patients found to have such neoplasms (Burton et al. 1998).

Resources for addressing health care errors

Several factors make addressing health care errors particularly challenging. Health care is an exceptionally dynamic enterprise, in which new risk is always being created and emerging. In addition, health care is in the midst of a transition from a cottage industry made up of independent, individual practitioners to a more cohesive industry in which a collection of processes can be thought of as interacting within a larger system (Berwick 1989). Until recently, even hospital care has been seen as a series of separate and unrelated interactions between health care professionals and individual patients (Avorn 1997).

Designing appropriate interventions for addressing health care delivery errors in Medicare requires an understanding of both the theoretical basis for error-reduction efforts and the available methods and mechanisms for reducing errors. In addition, an awareness of prominent initiatives geared toward reducing health care error is valuable, both to draw lessons and to identify ongoing private or public endeavors with which Medicare's efforts might be coordinated.

Error-reduction theories and lessons from other industries

Theories developed and used in other technically complex, potentially dangerous industries that have made safety and quality a high priority, such as transportation and energy, are attracting interest and gaining growing acceptance in health care. These industries have come to recognize that increasing safety requires changing the focus from individuals to processes and systems and creating an environment in which mistakes are seen as opportunities for learning rather than reasons for punishment.

Researchers in safety assert that human mistakes are often the inevitable result of poor system design rather than failures in professional care or diligence (Leape et al. 1998). This has led to a change in safety-conscious industries, from viewing individuals who make mistakes as the primary instigators of problems to seeing them instead as contributors or agents who trigger underlying defects in established processes, routines, or systems, or even as agents who are set up to fail by those underlying defects.

Increasing health care safety therefore requires paying attention to design of systems and processes used in patient care. Safety leaders in aviation and nuclear power have designed processes and systems that can improve consumer safety by reducing hazards and have worked to create a culture of vigilance. They have trained professionals to use methods designed to promote safety, to work in teams, and to solve problems in simulated emergency situations. They advocate designing systems to reduce opportunities for human error and introducing backup systems meant to keep adverse events from occurring as a result of those errors.

Many experts have observed that advancing safety in health care will require the industry to move beyond blame and punishment of individuals. Belief in the effectiveness of punishment as a means of error prevention in health care has posed challenges for implementing efforts to increase safety (Leape 1994). Rather than improving safety, the threat of punishment provides strong incentives for people to conceal errors when they do occur.

1 Of the total errors identified, 18 percent could not be classified.

2 Such findings do not indicate that quality of care is unchanged over time. On the contrary, advances in medicine have led to accurate diagnosis of many conditions that previously could not have been detected by either clinical exams or postmortem tests.

A shift from the culture of individual blame will be required to create an environment in which errors are seen as opportunities for learning. The health care industry must systematically avail itself of such opportunities if real advancement in error reduction is to occur. Doing so will require creating an environment in which investigating errors and taking active steps to improve processes, systems, and equipment are routine and expected activities in all health care organizations, facilities, and practices.

Methods and mechanisms for reducing errors

Recent advances in the tools available to address health care errors have created more opportunities to prevent them, learn from them, and take steps to avoid their recurrence.

Mechanisms for preventing or mitigating errors—such as reminder systems, equipment alarms, and processes designed to include redundancy at critical points—are prominent features of potentially hazardous and safety-conscious industries and are attracting increasing attention in health care. Some mechanisms are designed to keep errors from occurring, while others are intended to prevent the adverse events caused by errors or to mitigate the extent of any resulting harm.

Two types of methods can help turn errors into roadmaps for quality improvement. The first is root-cause analysis, a systematic assessment of system failures and other factors contributing to an incident in which safety is compromised. The second is pattern analysis, which uses data drawn from multiple incidents to find parallels or common features among errors.

The aviation industry has been looked to as a model for health care because of its success in systematically employing these types of mechanisms and methods to increase safety. The industry's safety initiatives are multifaceted. For example, airline safety is heavily regulated by the Federal Aviation Administration. In addition, the National Transportation Safety Board plays a crucial role in investigating accidents, and commercial carriers have individually built safety-conscious corporate cultures.

Another key component of the aviation industry's efforts is the Aviation Safety Reporting System, which was launched by the industry in 1975 to encourage self-reporting of safety problems and to aid in improvement. Under this system, pilots and others who are involved in or witness an incident in which safety was compromised (so-called near misses, not actual accidents) file a report describing the incident and suggesting actions that might help to avoid recurrence. These confidential reports are used to identify deficiencies and discrepancies in aviation safety policies, to support policy formulation, and to strengthen the foundation of research on human factors affecting safety. Fines and penalties are waived for those who report infractions, providing a significant incentive for voluntary participation. The program was initially regarded as unsuccessful, but incident reporting improved dramatically once administration was transferred from the agency that had regulatory authority to penalize those responsible for errors, the Federal Aviation Administration, to an intermediary agency, the National Aeronautics and Space Administration (Bermingham 1998). The system now receives 30,000 incident reports annually.

National health care error-reduction initiatives

A number of initiatives have been formed to address health care errors, including some that are national in scope and many others at the local or provider level. Notable examples of national initiatives include those designed to provide for reporting and sharing of information, both about individual instances of error and the effects of remediation efforts. Although most are quite recent efforts, already some lessons can be drawn that are applicable to error-reduction activities Medicare might undertake.

Sentinel events policy

Since January 1995 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has had a policy designed to encourage health care providers to self-report certain adverse events. Under this program, known as the sentinel events policy, accredited providers may voluntarily submit information to JCAHO on the occurrence of certain types of adverse events and the results of a root-cause analysis.[3] JCAHO takes steps to ensure that a root-cause analysis is conducted and that follow-up measures are taken to prevent recurrence. The organization also maintains information on the incident in its database, analyzes it to determine common underlying sources of error, and releases its findings periodically for quality improvement purposes. The program reportedly has been little used, which JCAHO attributes to two factors: the blame-oriented environment of health care delivery, which limits the extent to which incident reports are developed by providers at all; and legal concerns about the confidentiality of such information, which discourage providers from reporting information on incidents externally (O'Leary 1998).[4]

3 Reportable sentinel events under this program are those that affect recipients of health care and that have either: (1) resulted in an unanticipated death or permanent loss of function not related to the natural course of the patient's illness or underlying condition, or (2) involved suicide, infant abduction, infant discharge to the wrong family, rape, hemolytic transfusion reaction, or surgery on the wrong patient/body part. Incidents meeting the latter criterion are reportable even if the outcome was not death or major permanent loss of function. Near misses are not reportable.

4 As of December 17, 1998, only 374 sentinel events had been reported to JCAHO.

JCAHO's example seemingly affirms the theory that error reporting is unlikely to occur in an environment that penalizes those who acknowledge mistakes. The organization recently revised its policy on error reporting by providing time for the entities that report incidents to investigate them and take corrective measures. In the past, JCAHO itself would immediately conduct a review and place the facility or organization in which the sentinel event had occurred on accreditation watch. While the former approach had the intended benefit of alerting the public to potential quality problems, it strengthened existing disincentives for reporting.

JCAHO's program also highlights the importance of confidentiality as a prerequisite to information sharing. An important reason for lack of participation in the program is believed to be the concern of health care providers that sharing their root-cause analysis findings with accreditors would strip that information of any existing state-legislated confidentiality protections. JCAHO, therefore, is seeking federal legislation to provide national guidelines for confidentiality of this type of information (O'Leary 1998).

Patient Safety Improvement Initiative

The Department of Veterans Affairs (VA) has undertaken several activities to address the problem of health care errors as part of its Patient Safety Improvement Initiative. These activities include:

- founding a working group of public and private sector organizations interested in health care error reduction, known as the National Patient Safety Partnership;
- creating a patient safety improvement awards program for health care practitioners; and
- implementing a new health care error-reduction system.

This latter system, which became effective in June 1997, is known as the Patient Safety Registry and Reporting System. Modeled after the aviation industry's safety system, it includes:

- a patient safety handbook,
- a field-to-headquarters reporting mechanism for both sentinel events and unplanned clinical occurrences (near misses),
- a requirement to conduct root-cause analyses for such incidents, and
- an interdisciplinary expert review team at headquarters that provides feedback to medical treatment facilities and disseminates information to the rest of the VA system (Leape et al. 1998).

The system is applicable to all VA and contractor hospitals, nursing homes, primary care providers, home health programs, and domiciliary care facilities.

While the VA is different from Medicare in several important ways—notably in that it undertakes health care delivery, as well as payment—its efforts provide an example of how a government health program can take affirmative steps to address health care errors. By collaborating with other stakeholders, the VA ensures that its activities will be consistent with programs and activities sponsored elsewhere. By simultaneously implementing several initiatives (for example, the error-reporting system, the awards program, and the collaborative working group), the program demonstrates its commitment to the problem and increases opportunities for success.

Medication Errors Reporting Program

The Medication Errors Reporting Program provides a mechanism by which health care providers can report medication errors or near misses (anonymously, if desired) and obtain information about problems reported by others. The program is operated by U.S. Pharmacopeia in cooperation with the Institute for Safe Medication Practices—a nonprofit organization that works closely with health care practitioners and institutions, regulatory agencies, professional organizations, and the pharmaceutical industry to provide education about adverse drug events and their prevention. Reports submitted under this program—including those pertaining to confusion over similar looking or sounding drugs, miscalculation of dosage, and prescription errors—are shared with the Food and Drug Administration and the manufacturers of the pharmaceuticals involved. Case studies are also published to alert health care professionals about needs for practice changes and to ensure that industry and regulatory officials learn about elements of pharmaceutical labeling, packaging, or nomenclature that may foster errors.

Anesthesia Patient Safety Foundation

Health quality experts point to surgical anesthesia as the premier example of focused and successful error-reduction efforts in medicine (Leape 1994, Chassin 1998). This area of medicine may represent a natural leader in that errors in administering anesthesia—like airline crashes—tend to be transparent and knowable to others in that they can result in lasting and serious patient injuries, such as brain damage or death (Leape 1994). By using a variety of approaches, including improved patient monitoring techniques, examination of system factors that serve as a source of error, and development and use of practice guidelines, anesthesia-related deaths have been reduced to a rate of approximately 5 per million cases from a rate of between 25 and 50 per million cases in the 1970s and 1980s (Leape 1994, Chassin 1998).

The Anesthesia Patient Safety Foundation (APSF), formed in 1984 by the American Society of Anesthesiologists, has played

an important role in developing, fostering, and coordinating these efforts. The mission of the APSF is to ensure that no patient is harmed by the effects of anesthesia. The organization has sponsored research to better understand preventable anesthetic injuries, promoted programs designed to reduce the number of such injuries, and facilitated communication of information and ideas through its quarterly newsletter and other means.

National Patient Safety Foundation

The National Patient Safety Foundation (NPSF) is an independent not-for-profit organization founded in 1997 by the American Medical Association (AMA) and a broad partnership representing consumer advocates, health care providers, health product manufacturers, employers, payers, researchers, and regulators in a collaborative effort to measurably improve patient safety in the delivery of health care. The NPSF's core activities include:

- fostering research on human and organizational error and the prevention of avoidable patient injuries in health care;
- promoting the application of knowledge to enhance patient safety;
- developing information, collaborative relationships, and educational approaches that advance patient safety; and
- raising awareness and fostering communication to enhance patient safety.

The organization's research grant program made four awards in 1998. The NPSF has also organized a series of regional meetings on patient safety, conducted consumer opinion polls, held focus groups to learn about barriers to developing safety-oriented cultures in health care systems, and organized a workshop of safety experts from other industries to adapt knowledge, lessons learned, and innovative practices from other domains to health care.

Conferences on error-reduction theories and practices

Several organizations involved in patient safety work—including the American Association for the Advancement of Science, the Annenberg Center for Health Sciences, JCAHO, the NPSF, and the VA—cosponsored two multidisciplinary conferences on health care errors. The conferences, held in 1996 and 1998, provided a forum for examining and disseminating strategies for improving patient safety and reducing error.

In October 1994, the AMA, the American Nurses Association, and the American Society of Health-System Pharmacists held a conference focused on understanding and preventing so-called drug misadventures. This initiative generated recommendations for ways in which practitioners, health care institutions, health professional organizations, payers, regulators, and pharmaceutical manufacturers might foster understanding of the issues and minimize the problem. Among those recommendations endorsed by the conference's multidisciplinary panel were that hospitals should develop better systems for monitoring and reporting adverse drug events and that hospitals should approach medication errors as system failures requiring solutions (American Society of Health-System Pharmacists 1996).

Leapfrog Group

A group of health care purchasers widely recognized for developing innovative, value-focused relationships with health plans and providers has formed to identify and coordinate initiatives to improve patient safety. This so-called Leapfrog Group, which includes the Pacific Business Group on Health, the Buyers Health Care Action Group, and General Motors, has identified two issues for initial focus: incorporating evidence on the relationship between service volume and outcomes in determining the appropriate site of service and promoting the installation of computerized physician order-entry systems in hospitals to reduce the incidence of medication error.

Minimizing preventable errors under Medicare

Addressing preventable errors in the care provided to Medicare beneficiaries could improve quality of care and reduce program costs. Although successful efforts would likely yield systemwide improvements in health care, some evidence suggests that Medicare beneficiaries would benefit disproportionately from them. The Harvard Medical Practice Study showed that elderly hospital patients are at a higher risk for medical injury than younger patients (Brennan et al. 1991). In fact, hospital patients age 65 or older were found to be twice as likely to suffer adverse events as those between 16 and 44. The study's authors speculated that this finding could reflect elderly patients' propensity to have more complicated illnesses that require more interventions, as well as greater fragility associated with age.

RECOMMENDATION 3A

The Secretary should establish patient safety as a quality improvement priority for Medicare and should take steps to minimize the incidence of preventable errors in the delivery of care provided to beneficiaries.

While responsibility for addressing health care errors clearly lies with the health care delivery system, Medicare, as a prudent purchaser, might encourage or facilitate concentrated efforts in this area. Because work to address health care errors is largely in its infancy, Medicare can do much to provide leadership and to demonstrate that every health system stakeholder can benefit from participating in efforts to reduce the incidence of preventable errors. In devising error-reduction initiatives, the program should conduct small-scale tests of approaches that have been developed for other industries as well as for health care before adopting approaches for programwide use. To be successful, Medicare will need to coordinate its efforts with ongoing public- and private-sector initiatives to improve patient safety.

RECOMMENDATION 3B

The Secretary should support and make use of ongoing public and private error-reduction initiatives—including those that promote incident reporting by providers, analysis of root causes and patterns in occurrence, and dissemination of information designed to prevent recurrence—through Medicare's policies and quality improvement activities.

Reporting incidents of preventable errors in health care delivery is unlikely to become routine practice as long as providers fear that the information they disclose can be used against them in a punitive manner. According to Leape (1994), medical incident reports are not often filed because they are perceived as punitive instruments. Further, some courts have held that incident reports are discoverable and outside the protection afforded by peer review privilege, even when such reports are prepared to improve the quality of care furnished in an individual hospital rather than for external reporting (Liang 1999). In the absence of federal law to protect the confidentiality of information on incidents of preventable health care delivery errors, providers will face powerful incentives not to report this information, which limits the ability to learn from errors and prevent recurrence.

RECOMMENDATION 3C

The Congress should enact legislation to protect the confidentiality of individually identifiable information relating to errors in health care delivery when that information is reported for quality improvement purposes.

Federal legislation to establish confidentiality protections for this type of information is needed to promote the collection and use of data on incidents in which patients' safety is compromised. This type of legislation could help to promote development and use of incident-reporting systems by providers and plans, as well as participation in voluntary initiatives sponsored by private-sector accrediting bodies. It also could benefit Medicare if the program were to designate an external organization to serve as a repository for incident reporting, analysis, and dissemination of information. Such a law would neither help nor harm individual patients who are injured (compared with the status quo), but should help patients collectively by fostering the reporting of data that can be used to reduce the incidence of avoidable errors in the future.

Any steps to encourage confidential reporting of individually identifiable information raise concerns about patient privacy that must be addressed simultaneously. Numerous efforts are under way to resolve concerns about the appropriate use of individually identifiable health and medical data; however, resolving those concerns to the satisfaction of all stakeholders has proved challenging.

Medicare's policies for addressing errors and adverse events

At present, Medicare does little to influence the incidence of errors in the care provided to program beneficiaries. The program relies largely on systems established by the medical profession and private-sector accrediting bodies to provide channels of accountability for health care providers, organizations, and facilities. In this respect, Medicare is not unlike most health care purchasers, both public and private.

Medicare's contractors for quality assurance and improvement activities, the state-based quality improvement organizations (QIOs), are responsible for handling Medicare's quality-related complaints, including those from patients and practitioners.[5] However, individual providers or beneficiaries have no affirmative duty to report complaints, safety concerns, or adverse events. QIOs that receive information about an adverse event or error investigate the incident and use administrative databases and hospitals' medical records to determine whether a pattern of similar cases exists. Under their present arrangements with the Health Care Financing Administration (HCFA), the organizations focus primarily on identifying opportunities for improving quality from a population perspective, rather than on specific instances of substandard care provided in a particular incident.

Medicare also requires that providers adhere to the program's conditions of participation (COPs) in order to be eligible for payment, and that participating plans adhere to Medicare+Choice program rules. Medicare's rules generally require health plans and health care facilities to maintain ongoing internal quality assurance systems designed to actively identify, investigate, and resolve quality problems. Medicare currently has little ability to evaluate the effectiveness of those required internal quality assurance systems. Instead, the program prescribes and assesses certain structural and procedural elements of those systems that are believed to enable them to be effective in ensuring and improving the quality of care.

5 The organizations now prefer to be called quality improvement organizations because they believe this appellation denotes the scope and orientation of their current responsibilities better than does the term used in statute and by the Health Care Financing Administration: peer review organizations.

Harnessing Medicare's tools for addressing errors

Medicare has a wide range of policy levers that it could employ in new initiatives or refocused efforts to reduce errors in health care. Some are more appropriately used to address specific, targeted care delivery issues, while other, blunter levers might be used to draw resources and attention of the health care community to the issue of errors.

RECOMMENDATION 3D

The Secretary should consider opportunities for minimizing avoidable errors in health care delivery through coverage and payment policies, quality measurement initiatives, and quality improvement programs.

Coverage and payment policy

Decisions about what is paid for and how to pay are among Medicare's most powerful tools for influencing care. Coverage decisions stand to affect error rates when new technologies for diagnosing or treating illness could help to reduce opportunities for mistakes. Although Medicare's current payment formulas do not account for errors or other dimensions of health care quality, in the future, payment might be used to provide incentives for health care organizations and providers to invest in systems designed to minimize opportunities for unchecked human error or to identify errors that are systemic in origin.

Quality measurement for public reporting

By choosing which performance data to collect and publicize, Medicare has considerable power to influence where health care providers will concentrate their resources and attention. The Medicare HEDIS reporting requirements represent the clinical and nonclinical areas for which health plans are accountable to HCFA for their performance.[6] The measures of health care quality included in the reporting requirements are ones for which better documentation and reporting will yield better scores, such as flu shot and diabetic eye exam rates. HCFA could conceivably choose to require measurement and reporting of error rates, but doing so would create substantial disincentives for accurate and complete data documentation. Instead, the agency might focus on developing and using performance measures designed to assess the extent to which providers are taking steps to address errors. Doing so could provide beneficiaries with a basis for differentiating plans' and providers' efforts without penalizing those who acknowledge error.

Quality improvement programs

By designating specific clinical and nonclinical areas for health care quality improvement, Medicare can influence which areas will be subject to the focused improvement efforts of health care providers and plans. Medicare's quality improvement organizations are accountable to HCFA for demonstrating net quality improvement in these specified areas at the state level. QIOs typically use tools such as provider profiling, feedback, and education in their efforts to bring about changes in health care delivery.

RECOMMENDATION 3E

The Secretary should work with providers and other stakeholders to identify and promote effective and efficient processes, structures, and activities for reducing preventable errors and to set progressive targets for improvement in patient safety through Medicare's quality improvement programs.

MedPAC supports defining and regularly updating numerical targets for improving patient safety. Through this approach, Medicare could establish a nonpunitive environment for improvement while sending the message to beneficiaries that the program is committed to continual advancements in safety. To increase the likelihood of effectiveness, however, implementing such an approach in Medicare would require legislative authorization to establish improvement incentives (financial or otherwise) geared toward health care providers. The current system lacks mechanisms by which the program can hold providers directly accountable for improving their performance.[7]

In addition to targeting specific types of health care errors through the QIOs, Medicare might also implement an error-reporting system as a new tool for health care quality improvement. Under such a system, the QIOs could be called on to:

- collect information reported by providers on errors that result in adverse events or potential events, including an analysis of the factors contributing to the errors;
- analyze reported information to identify patterns or common themes; and
- disseminate information obtained through the analyses to help providers identify changes in processes or other steps necessary to avoid recurrence.

One important factor predicting the success of such a program would be providers' willingness to report complete and accurate information on errors to the QIOs. In past years, QIOs have undergone a dramatic transformation in terms of their role and activities, moving

6 HEDIS, the Health Plan Employer Data and Information Set, is a set of widely used measures of health care quality and health plan performance promulgated by the National Committee for Quality Assurance.

7 The Commission recommends that the Congress provide legislative authority to test use of performance incentives under Medicare. See Chapter 2.

from punitively oriented retrospective case review to a more collegial mode as a quality improvement resource and partner to health care providers. Technically, however, QIOs retain some role in identifying and reporting to HCFA on specific quality problems. As the aviation industry's experience demonstrates, this policing function may affect the willingness of providers and health plans to report errors to QIOs. The QIOs do have the advantage of statutory protection from having to release information pursuant to their quality activities, however, allowing them to ensure confidentiality to providers who might otherwise harbor liability concerns about sharing adverse information.[8] Federal law also provides this type of protection for providers who disclose information to the QIOs, although some have raised questions about the extent of providers' awareness that they have this protection.

Potential limitations on national use of data also raise questions about the potential role of QIOs in an error-reporting program. Stringent legal restrictions on how the organizations use individually identifiable (including provider-specific) information curtails the extent to which the groups can share information with each other or pool data in a common repository for quality improvement purposes. Because QIOs and HCFA are now preparing to implement new contractual requirements to conduct national quality improvement projects, the agency and its contractors are working to find out to what extent and how data sharing might be possible.

Other issues associated with crafting a formal error-reporting system for Medicare include developing reporting incentives, establishing accountability for reporting, and disseminating information to support error-reduction activities. The program's own fraud and abuse initiative—under which those who detect problems, self-report, and institute steps to avoid future recurrence can avoid penalties—may provide a model for creating reporting incentives. Those guilty of defrauding the program face potential fines and legal penalties, the threat of which can make clemency an attractive incentive for self-reporting of mistakes. A comparable, credible threat for failing to report errors would have to be established, presumably a fine or other penalty. Accountability for reporting errors might be modeled after the aviation industry's safety system, requiring anyone with relevant knowledge to make a report in cases where errors occur. Alternatively, the burden of accountability might appropriately rest with the facility or plan associated with the incident. Furthermore, medical professional societies and industry groups might play a role in disseminating information by working with QIOs to inform their membership about various patterns of error or safety issues identified through an analysis of reported error data.

Program participation requirements

Medicare's participation requirements are important because they serve as HCFA's primary vehicle for making substantive requirements of health care providers and plans, but they are limited in important respects. They are not easily changed to accommodate new quality improvement goals. They also are infrequently updated, in part because of the extensive rulemaking process that HCFA must adhere to in promulgating these standards.[9] This characteristically slow process is designed to facilitate input from all stakeholders and interested parties, but it may result in standards that are outdated or otherwise out of step with comparable private-sector norms.

RECOMMENDATION 3F

The Secretary should not establish requirements that specify maximum tolerance rates of errors in health care delivery under Medicare's conditions of participation for health care providers.

Medicare's program participation requirements could address health care errors in at least two alternative ways: by specifying maximum error rates or by specifying required structures, process, or activities to be used to address errors. The Commission finds the first approach to be overly prescriptive and not in keeping with Medicare's objective of promoting constant improvement in the quality of care beneficiaries obtain. However, to the extent that certain structures, processes, or activities have been identified as effective and efficient, MedPAC supports including requirements for their use in conditions of participation for providers and in program participation rules for health plans.

Addressing medication errors in Medicare

A recent national study suggested that medication errors are on the rise, with the total number of related deaths more than doubling between 1983 and 1993 (Phillips et al. 1998). This rise may be associated with increasing complexity in drug ordering, the proliferation of new drugs, and the expanding role of pharmaceuticals in patient care.

Studies suggest that taking steps to avoid preventable adverse drug reactions offers hospitals the potential to achieve considerable savings, making prevention of medication errors an attractive quality improvement goal in a time of constrained resources. One recent study estimated the annual costs of preventable ADEs at $2.8 million in each of two teaching hospitals, out of an

8 Quality review study information with patient identifiers is not subject to subpoena or discovery in a civil action, including an administrative, judicial, or arbitration proceeding (42 CFR § 476.140).

9 For example, HCFA proposed new conditions of participation for hospitals in a notice published in the December 19, 1997, Federal Register. Because the agency is still reviewing over 61,000 comments received on this proposal, no publication date for the final rule has been announced. The standards were most recently updated in 1986, following a six-year public comment review process.

estimated total of $5.6 million per hospital in total expenditures due to ADEs (Bates et al. 1997). These estimates represent only the costs of additional patient care in the hospital, not hospital expenses associated with litigating cases and remunerating injured patients. They also do not account for costs directly borne by injured patients.

Order-entry systems offer potential to reduce medication errors

Studies have shown that improving the systems for ordering and administering drugs in hospitals can successfully prevent many ADEs from occurring (Leape et al. 1995). Given the need for continual system refinement and variation in development and implementation costs, it is difficult to determine whether computerized systems designed to prevent ADEs are cost effective for individual hospitals, although they are much more likely to be so if patient and social costs are factored into the analysis.

Some hospitals have now installed computerized systems that display warnings in cases of drug interactions, known drug allergies, or incorrect dosages in response to medication orders entered by physicians. A computerized order-entry system used in one large tertiary care hospital was shown to decrease the rate of serious medication errors by more than half, resulting in savings to the hospital of an estimated $480,000 annually in direct patient-care costs (Bates et al. 1998). Another such system detected opportunities to reduce ADE-related injury at a rate of 64 per 1,000 patient admissions (Raschke et al. 1998). Yet another program, designed to assist physicians in prescribing antibiotics, decreased mortality among patients treated with antibiotics by 27 percent while substantially reducing both antibiotic costs per patient treated and overall antibiotic acquisition costs (Pestotnik et al. 1996).

But considerable investments may be required if all hospitals are to develop the capacity to implement and operate such systems. Prerequisites for a computer ADE alert system generally include:

- an integrated computerized database that includes clinical, pharmacy, and laboratory data;
- the ability to program the system to generate alerts when opportunities to prevent injury occur; and
- reliable clinical systems for physician notification (Raschke et al. 1998).

Developing, instituting, and operating computerized systems designed to reduce medication errors can be costly. While costs will vary depending on institution size, system design factors, extent of need for health data system development, and ability to replicate existing systems, one group responsible for developing and implementing such a system recently reported a range for development costs of anywhere between several hundred thousand and several million dollars (Raschke et al. 1998).[10] Development of another system was estimated to cost $1.9 million, with maintenance costs of $500,000 per year (Bates et al. 1998).

Medication-error policy options for Medicare

Although Medicare might consider a number of approaches to encourage hospitals to reduce medication errors, all options present operational challenges. Prominent among the policy changes Medicare might make are:

- changing the conditions of hospital participation, and
- creating additional incentives for hospitals to reduce medication error rates.

Other options include promoting medication-error reduction efforts through the quality improvement projects sponsored by Medicare's QIOs.

Conditions of participation Medicare's conditions of participation for skilled nursing facilities and proposed new COPs for hospitals both include requirements relating to medication errors. Medicare's COPs require long-term care facilities to ensure that residents are free of any significant medication errors and that the overall medication error rate is under 5 percent. HCFA proposed adopting similar requirements for hospitals in new and revised Medicare COPs published in December 1997. Under the proposed COPs, hospitals participating in Medicare would not be permitted to exceed a medication error rate of 2 percent and would be required to establish a "zero tolerance" policy for "significant" medication errors. These changes to the COPs reflect HCFA's initiative to replace requirements that prescribe systems and procedures with new standards focusing on the results of care provided to patients (HCFA 1997).

MedPAC joins others in opposing HCFA's proposed standards for medication errors in hospitals and calls for the agency to retract similar standards now in place for skilled nursing facilities. The American Society of Health-System Pharmacists, the JCAHO, the American Hospital Association, and other organizations criticizing HCFA's proposed hospital standards have raised questions about the specific rate designated—in that it appears to be lower than that achieved by the best performers in the industry—and the potential effectiveness of setting an overall error rate as a way of reducing ADEs. Critics have also noted that the standards could create the impression that HCFA implicitly sanctions a certain level of errors, a notion seemingly at odds with consumer expectations of fail-safe, error-free hospital care and the aim of public policy (Manasse et al. 1998).

10 Radiology technicians responded to alerts designed to prevent radiocontrast media nephrotoxicity.

A group of prominent proponents of health care safety has suggested an alternative to HCFA's approach to addressing medication errors (Manasse et al. 1998). The group called for HCFA to require each hospital to establish and conduct an active, interdisciplinary quality improvement program focused on preventing and eliminating medication error that includes:

- a standard definition of medication error;
- an ongoing process for measuring medication errors, following up on their root causes, and instituting safety mechanisms to eliminate repeat incidents;
- a periodic analysis of the safety of medication use, coupled with education and training of staff;
- identification of the most hazardous aspects of hospital medication use and systematic efforts to reduce those hazards; and
- reporting of serious medication errors to existing, voluntary national reporting programs.

The pharmacy profession also has developed guidelines and standards of practice that address the prevention of medication errors, including approaches that health systems can use to develop systems for preventing errors and for managing errors that have occurred (American Society of Hospital Pharmacists 1993). Given the early state of developing and instituting systems and processes for reducing error, the Commission believes that process-oriented standards such as these represent a more appropriate way of addressing medication error in Medicare's conditions of participation.

Financial incentives Given the potential for significant benefits to beneficiaries and to the program by reducing medication errors, Medicare might establish financial incentives to encourage hospitals' efforts. This approach offers the advantage of rewarding quality improvement, not often seen in a regulatory environment.

Incentives to reduce medication error might be created in several different ways. For example, Medicare might explicitly subsidize a portion of hospital investments in computerized ordering systems, although this option risks a high likelihood of administrative burdens and delays associated with such factors as defining eligible systems and overseeing the appropriate use of the funds. The indirect approach of offering financial rewards or bonuses to hospitals that reduce error rates or achieve established thresholds avoids the drawbacks of the subsidy option but presents its own operational challenges, including problems associated with defining errors adequately, ensuring accurate reporting, and setting appropriate target rates.

Increasing autopsies to identify and learn from errors

Increased use of autopsies, together with improved collection and use of information derived from the procedure, could be instrumental in systematic efforts to reduce errors. Despite seeming consensus among the medical community and other stakeholders that autopsies have great value for public health and health care quality, use of the procedure is waning and use of the information derived from those performed is limited.

Medicare interventions in autopsy use are justified both by the historic role the program has played in financing health-related costs of general benefit to society and by the program's interest in beneficiary care: beneficiaries currently represent about three-fourths of all hospital deaths, and information gleaned from autopsies could benefit that population's care significantly.

The Commission believes that information derived from autopsies offers significant potential for use in efforts to reduce errors and improve quality. More information is needed, however, to determine the steps Medicare should take to promote use of autopsies and the information they provide.

RECOMMENDATION 3G

The Secretary should fund research to study appropriate use of autopsies and to evaluate approaches for using information derived from autopsies in health care quality improvement and error-reduction initiatives.

Autopsies can yield multiple benefits

Purported benefits of autopsies have often been cited. Autopsies can be a tool for learning, playing a role in the advancement of medicine as a whole, the training of medical students, and the continuing education of physicians. They provide a means of determining diagnostic accuracy and can serve an important role in quality control. Researchers have noted that autopsy findings contributed to important medical breakthroughs in understanding diseases such as AIDS and Alzheimer's disease (Lundberg 1998). Autopsies can assist in evaluating the effectiveness of new drugs and treatments. They also can provide family members of the deceased with important information about hereditary diseases. Furthermore, they can help to improve the accuracy of public health statistics by providing a way to detect previously undiagnosed disease.

Determining the appropriate use of autopsy is hampered, however, by a lack of systematic documentation and quantification of autopsy benefits. Numerous experts have called for data collection and analysis designed to develop cost-benefit ratios and for prospective, controlled research designed to document the benefits of autopsies (Marwick 1995, Hill 1996). Without such evidence, it is difficult to set meaningful, objective standards for appropriate use. Furthermore, in an era when new tools for assessing and improving quality are continually becoming available, autopsies may be held to a higher test of value (O'Leary 1996).

Insufficient use of information from autopsies

Numerous observers have commented on the need to do more to ensure that autopsy data become usable information and that this information is used systematically to improve health care. Current variations in data handling and communication procedures—such as the proliferation of different forms for obtaining consent for autopsy and reporting autopsy results—present barriers to doing so (Hill 1996). The Institute of Medicine's Health Sciences Policy Board identified several issues needing further investigation, including the collection and reporting of autopsy data and sharing and use of information derived from autopsies beyond the practice of pathology (Setlow 1996).

Autopsy rates declining

While the ideal autopsy rate is unknown, numerous experts have suggested that current rates, which have been dropping steadily over time, are insufficient.[11] Because of problems in reporting data, exact rates are difficult to pinpoint, but autopsy rates generally have fallen from an estimated 50 percent of hospital deaths in the 1960s to recent averages of approximately 10 percent to 20 percent in teaching hospitals and 5 percent in other community-based hospitals (Marwick 1995). Many hospitals have autopsy rates at or near zero (Lundberg 1998). Data from the Centers for Disease Control and Prevention (CDC) illustrate the continuing decline in the percentage of deaths for which autopsies were reported. In 1990, the percentage was 11.2, but it had dropped to 9.4 percent by 1994 (CDC 1999).[12]

Determining appropriate autopsy rates requires considering the numerous potential uses for information from autopsies. Sampling statisticians could determine an appropriate autopsy rate to monitor errors in health care delivery based on the estimated frequencies of various types of errors. Such rates might in turn be augmented to support other information-seeking purposes. Medical professional societies have developed guidelines defining the circumstances under which stakeholders could reasonably expect an autopsy to uncover additional information of value.[13]

Reasons for declining autopsy rates

Industry observers, analysts, and the media have reported many reasons for the dramatic decline in autopsy rates. Surveys of Chicago-area hospitals conducted by the Institute of Medicine of Chicago in 1993 and 1994 found four primary reasons for the decrease autopsies (Hastings and Andes 1997):

- lack of direct reimbursement;
- retraction of defined industry standards for minimum autopsy rates;
- fear of inducing litigation, including malpractice suits; and
- technological improvements in diagnostic techniques that provide ways of obtaining information comparable to that provided by autopsies.

Other industry observers have advanced other theories that may help to explain the autopsy's decline. For instance, a study that yielded data from in-depth interviews with hospital pathologists over a 30-year period suggests that the role of chief pathologists has changed, with an increasing proportion of their time devoted to duties other than autopsies, notably laboratory work (Hastings and Andes 1997). The College of American Pathologists asserts that many hospitals do not provide state-of-the-art facilities and technology for the autopsy and that many hospital autopsy suites do not have adequate environmental engineering to protect staff from pathogens (Wood 1999). Others have suggested that eroding relationships—between physicians and patients, and in families increasingly separated by distance or other factors—have contributed to decreased autopsy rates by reducing the willingness to request or grant permission for autopsy.

Payment Because health insurers tend to pay for autopsies either indirectly or not at all, hospitals generally do not have financial incentives to supply them. Insurers reportedly fail to cover autopsies for several reasons:

- they are not a health care service performed to improve the health or functioning of a patient,
- health plan membership and insurance benefits normally cease upon death, and
- other types of payments to hospitals are presumed to include hospital autopsy costs and other overhead expenses (Chernof 1996, Marwick 1995).

Medicare pays hospitals for autopsies indirectly, considering them an allowable cost associated with hospital administration and quality control rather than a patient care service. The program's payment for autopsies is included in an unidentifiable amount in the diagnosis related group payment to the hospital.

Like hospitals, pathologists also often lack direct financial incentives to perform autopsies. Because autopsies are not a covered service under Part B,

11 An informal poll of autopsy conference attendees revealed widespread support for a rate of 20 to 25 percent of hospital deaths, although this result likely reflects the historical precedent of these rates as performance standards (Hill 1996).

12 The CDC stopped collecting data on autopsy provision in 1995, in part because the statistics, collected through death certificates, were known to be unreliable.

13 The College of American Pathologists, for example, has issued guidelines for determining which cases of hospital death warrant seeking permission for autopsy, including all obstetric, perinatal, and pediatric deaths, as well as deaths in which the cause is not known with certainty on clinical grounds (College of American Pathologists 1997). Other groups also have endorsed these guidelines (American Society of Clinical Pathologists 1997).

Medicare does not pay physicians for performing them. Instead, pathologists negotiate payment with hospitals for those services considered to be provided to the hospital, rather than to an individual patient.[14] According to the American Society of Clinical Pathologists, hospitals' arrangements for paying pathologists vary (Linder 1998). Some hospitals pay a flat fee that encompasses designated pathology services (such as providing autopsies, serving on committees, and overseeing laboratory services). Others budget for a certain number of autopsies to be performed annually and pay the pathologist a prospective amount based on the budget assumption. In some cases, pathologists work for hospitals under a fee-for-service arrangement.

Standards The lack of accountability for performing autopsies under current public- and private-sector requirements for hospitals is another factor often cited as contributing to the decline in autopsies. Medicare's current hospital conditions of participation do not specify minimum autopsy rates; previously required minimum rates were eliminated in 1986, when the standards last were updated. JCAHO, a private-sector accrediting body, dropped its standards for hospital autopsy rates—20 percent for community hospitals, 25 percent for teaching hospitals—in 1970 (O'Leary 1996).[15]

Some standards prescribing hospital autopsy rates remain in effect, although there is evidence they are not widely followed. Data from the Residency Review Committee for Internal Medicine show that 51 percent of the 386 internal medicine residency programs reviewed for accreditation from January 1991 to May 1994 were cited for failing to conduct autopsies on at least 15 percent of deaths, as required (Schatz 1995). The potential for adverse accreditation status resulting from failure to meet the standard apparently was insufficient to attain compliance.

Other accreditation standards and Medicare participation requirements address autopsy performance without specifying rates. JCAHO's current standards require that hospitals establish criteria for appropriate use of autopsies, ensure medical record notation of efforts to obtain permission for autopsy when the procedure is indicated, and use findings from autopsies in quality assurance activities. Under Medicare's current requirements, hospital medical staff must attempt to secure autopsies in unusual deaths or deaths of medical, legal, or educational interest; hospitals must define the mechanism used to document permission to perform an autopsy; and hospitals must have a system for notifying the medical staff generally, and the attending practitioner specifically, when an autopsy is performed.

Medical advancements Some medical professionals believe that advancements in diagnostic ability have made the autopsy obsolete, although others have refuted that notion. Consistent evidence of discord between pre- and post-mortem diagnoses in studies conducted over most of this century has been cited as evidence that technological advancements have eliminated neither the ability to gain valuable information through the autopsy nor the need to do so (Lundberg 1998).

Liability considerations To the extent that health care professionals believe autopsies are likely to uncover mistakes in health care delivery, hospitals and physicians may avoid autopsies because of concerns about the potential to incite or support malpractice charges. An October 1998 broadcast of the news program *60 Minutes* reported that some hospitals seemingly act on liability concerns by employing risk managers who advise families of deceased patients against requesting an autopsy (CBS 1998). Some experts in the professional liability industry suggest fears of autopsies are unfounded, and that, in fact, autopsy often strengthens a physician's defense (Wood 1998).

Policy options for promoting appropriate use of autopsies

Medicare policymakers should consider changing the hospital conditions of participation, revising payment mechanisms, or taking other steps to promote autopsy use. Quality and performance measurement initiatives offer the potential to direct resources and attention to appropriate autopsy use, particularly if implemented with other actions. Because many factors seem to have contributed to autopsy decline, a single intervention might be insufficient unless it can stimulate other changes in the industry.

As a health care purchaser, Medicare is more directly positioned to promote increased use of autopsies than to ensure better use of the information they provide, although the latter step is crucial if autopsies' full potential is to be realized. Steps by Medicare to increase the utility of the service as a quality improvement tool might be considered. For instance, HCFA might require standard protocols for classifying unexpected autopsy findings and formally feeding back those findings to hospitals' quality assurance programs. Alternatively, HCFA might require that hospitals report such data to the program's QIOs for use in focused quality improvement initiatives. The medical profession and other interested parties must meet the challenge of taking the necessary next steps to ensure appropriate information use, however.

14 Pathologists have expressed concerns about their ability to negotiate reasonable payments from hospitals for the services they provide to the hospital (such as laboratory management or autopsy performance) that are covered under Medicare Part A, but not Part B.

15 JCAHO originally intended these rates to be guidelines for hospitals, but examining boards in medical specialties, hospitals, and practicing physicians interpreted them as mandatory.

Change conditions of participation Whether to reinstitute minimum autopsy rates in Medicare's conditions of participation has been the subject of heated debate. If Medicare were to do so, as some autopsy advocates have proposed, the agency might attempt to address some of the concerns that led JCAHO to eliminate its former standards and that presumably also factored into HCFA' s subsequent retraction. Among the concerns were that:

- the standards did not necessarily represent the appropriate rates for all hospitals;
- hospitals undertook autopsies unselectively to meet the minimum requirements; and
- the standards failed to consider appropriate differences in autopsy use among various divisions within hospitals (O'Leary 1996).

To address these concerns, new COPs might provide greater flexibility for unusual circumstances, allowing hospitals to justify deviations from established standards when patient case-mix or hospital orientation warrant. HCFA also might consider allowing outsourcing autopsy services when hospitals lack capacity to conduct autopsies on site.

Medicare might strengthen hospital COPs relating to autopsy use without specifying minimum rates. Examples of potential changes include hospital autopsy policies suggested by the American Society of Clinical Pathologists (1997), namely:

- instituting an Office of Decedent Affairs or equivalent to help hospital staff and patients' families cope with death in the hospital, to prepare families for the autopsy request, and to institute methods for improving the autopsy consent rate;
- developing an informational pamphlet for the family members of deceased patients that describes the autopsy procedure and its value; and
- conducting in-service programs for nurses and social workers to ensure that these personnel help to obtain autopsy consents.

Reconfigure payment arrangements Interested parties assert that promoting adequate autopsy use will require changing payment arrangements, irrespective of other steps taken. The College of American Pathologists states that without such change, calling for more autopsies will only frustrate pathologists, other physicians, hospitals, and institutional administrators (Bauer 1994).

Medicare might consider at least two types of payment changes. First, Medicare could pay pathologists directly for the autopsies they perform by making autopsy a Medicare-covered service, reimbursed under the physician fee schedule. Such a change would appear to make autopsy unique among the program's covered services in that it is not undertaken for the medical benefit of a patient. Second, Medicare might make bonus payments to hospitals that achieve target autopsy rates, an approach that raises different questions, such as whether to impose financial penalties on hospitals that fail to improve autopsy use and whether to introduce other types of performance-based payments.

Costs to Medicare of changing autopsy payment arrangements will depend on several factors, including the level of reimbursement and extent of use. Hospitals' costs and physician work associated with autopsy performance are believed to range widely, depending on the comprehensiveness of the autopsy and the extent to which ancillary diagnostic procedures are required. Fixed costs also vary by hospital, in that many autopsy suites require upgrading to meet recently revised occupational health standards for infectious disease protection. At present, inadequate data exist to assess the costs to Medicare of making direct payments to pathologists for autopsies.

Make autopsies a quality improvement focus Medicare's quality improvement programs offer another avenue for promoting appropriate autopsy use. Medicare could identify increased use of autopsies as one of its quality improvement goals, thereby requiring quality improvement organizations to develop and run improvement projects focused on autopsy use. This approach would create meaningful incentives for QIOs, because under the most recent contractual arrangements, HCFA now holds QIOs accountable for demonstrating improvement. It is not clear, however, that QIOs have sufficient leverage with providers to adequately address or overcome the underlying reasons for the decline in autopsy rates.

Incorporate autopsy standards into performance measurement activities Although not an immediately viable option, in the future Medicare might use its new performance measurement systems to attain accountability for appropriate autopsy use. Doing so would require defining appropriate performance measures for autopsy use and incorporating those measures in a performance measurement and reporting system for hospitals.

Some developments in this area may be forthcoming. At the behest of the College of American Pathologists, the AMA's board of trustees recently referred a resolution encouraging use of autopsies in performance measurement and quality improvement activities to the Performance Measurement Coordinating Council, a group designed to coordinate the quality measurement activities of three leaders in the accreditation industry: the JCAHO, the National Committee for Quality Assurance, and the AMA (Wood 1998). ■

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